Program (FUSRAP) site did not find widespread contamination, probably due to the use of the salt bath. For conditions related to dose, those likely compensable are lung cancers in nonsmokers, and skin cancers are compensable. Kidney cancer may be compensable.
Ziemer: *Will the methodology account for the greater chemical than radiological toxicity of natural uranium?* Yes, but that pertains to a Sub-part D claim, not this task.
Melius: *So ORAU went through a number of the AWE sites to develop the site profiles?* Yes, and four more sites are still in development. Mr. Elliott added that these were chosen according to the number of claims to date, in order to have the maximum impact of addressing the "low hanging fruit" (e.g., this site had 300 claims) while building and testing the models.
Griffon: *How are the DOE site profiles likely to differ from those of the AWEs?* Dr. Neton said that most DOE sites will have personal monitoring data as well as processing data. That can flesh out these profiles, which are now mostly based on whole-year data. Dr. Toohey added that ORAU is creating look-up tables for processes and x-ray exposures, as well as the minimum detectable limits for sites. For example, Hanford, Rocky Flats, the NTS, etc., were major plutonium facilities. Those lookup tables are necessary to do dose reconstructions for people who had biomonitoring done.

Public Comment
Ms. Jeannie Cisco (phone 740-289-2045) was employed at the Portsmouth Gaseous Diffusion Plant (GDP), and is a compensation representative for the PACE Union Local 5-689. She works in the PACE Medical Protection Program and assists the members' EEIOCPA claims. She reported the concerns of claimants with the interview process. PACE advised the claimants to prepare written answers before the phone interview to ensure that the most information could be provided as accurately as possible. One person did so and spoke to the interviewer for about 3 hours in the first interview. He was pleased with the interviewer's patience and attention, but the draft report was overly condensed and held inaccuracies. The interviewer was clearly not familiar with the processes. When the person called to complain, he was told by the interviewer that the computer only had so much space for answers per question asked. He then contacted Ms. Cisco's office and they tried to condense his written answers. The second interview was 45 minutes long. Comments provided were included, but there were still incomplete sentences and inaccuracies (e.g., coal recovery versus cold recovery).

Ms. Cisco urged that NIOSH tape interviews with the claimants' permission in order to ensure maximum accuracy. Clearly, she thought an audit to be needed by the ABRWH to ensure QC and mid-course corrections as needed. She advised that the claimants be allowed to itemize the records needed, and felt that the claim form is problematic for widows/widowers, whose spouses were not allowed to discuss processes with their families.

Mr. Greg Malone, of Local 252 of the National Chemical Workers Union, represents the Center for Worker Safety Information. This is funded by a DOE grant and conducts health and safety training; he is a coordinator. He stated that asking an 80-year-old woman what her husband did is contrary to the reality of the culture. In the 40s and 50s, anyone who said they worked at Oak Ridge was not asked any other questions.

He had heard Dr. Tara O'Toole, a DOE Assistant Secretary, testify to Congress that DOE monitoring results were "junk." He agreed, noting that Y-12's air monitoring was done 8-12' above the floor, and only in the mid-1980s was lowered to the breathing zone. After that, "the counts went sky high." He also asked how the fact could be addressed that in the 1940s and 1950s, workers were routinely told to leave their dosimeters outside when working on a "hot" job. He asked how the perception can be avoided that the "fox is still guarding the hen house?" DOE is still providing the data and funding the process. In fact, in Mr. Malone's opinion, DOE should be the one required to prove they did no harm, not the claimant that they did.

Dr. Ziemer recalled that one member of the public said at a previous meeting that claimants had to provide the data, although it was clarified that they do not. He appreciated the good points raised, which have had been discussed by the Board before. The dose reconstruction processes are trying to gather supplementary data to address those issues.

Dose Reconstruction Workgroup Report/Changes Made

Mr. Mark Griffon, Chair of the Dose Reconstruction Workgroup, reviewed the three documents discussed by the workgroup and by the Board during the December conference call. The latest draft (January 2003) reflected the changes made in the Workgroup and the conference call. He outlined those that were major.

Attachment A, Request for Contract

- Page 3: A reference value will have to be added to Project Planning.

  To Section H, "The review panel will present their justification for contractor(s) selection to the Board prior to the contract award" was added.

  Section P, page 4: Definition of the technical panel members was left open except for one advisory Board member. Also discussed was whether among the other members should be a representative from other federal agencies as well as NIOSH. Mr. Elliott clarified that one OCAS staff member will be on the review panel as well as others from other federal agencies (not DOE) who are trained in contract procedures. Panel members other than the Board member will not be identified, but their affiliation may be identifiable. Mr. Elliott agreed to check on whether the latter is possible.

Attachment C

- Page 3, Section A: Text included the projected breakouts of expected cases to review years one through five.

  Page 5, Section 2b: Mr. Elliott asked that the phrases added on re-interview be removed, because that would require at least the Department of Health and Human Services (DHHS) and possibly OMB clearance before the program could proceed. Even adding *"pending OMB approval"* would still require OMB and/or DHHS approval.
  - Griffon: The ABRWH should commit to proceed with this, at least in principal, because if not included here, it may not be done. The current plan is only to review the summary form of the interview rather than whether the interview itself captures everything

accurately and sufficiently. Ziemer: Perhaps a third, non-specific, point could be included, requiring the contractor to assist with other work in the future to evaluate the process.

- Mr. Elliott appreciated Ms. Cisco's comments related to this question, and wished they had been brought directly to NIOSH. The survey instrument and interview approach were fully vetted in DHHS and were designed to capture all information, even acknowledging the site secrecy that was cited in public comment. There are three interview forms, and the one for survivors also asks about co-workers who could add information. Among the process tools are a follow-up report, a final review by the claimant, and their signing of the OCAS-1 form. NIOSH welcomes an audit of all these procedures, and can implement such new procedures after the OMB clearance is in place.
- Andrade: *Taping the interviews seems advantageous. Would a comparison by an auditing body of the tape to a transcript/report require OMB clearance?* Elliott: Whether OMB clearance is required depends on whether there are changes in the questions, going back to the interviewee, etc. These considerations led to NIOSH's decision to not tape.
- Andrade: *Then, perhaps it would be more practical for both the interviewer and the auditor to summarize what they thought they heard and compare those for accuracy. Any discrepancies would prompt a follow-up phone call to the interviewee to straighten that out.* Mr. Elliott found this suggestion to have merit. This would be part of the follow up to ensure that the information needed is in hand to pursue the claim, and not require OMB clearance. Such methods are more practical than requiring a follow-up audit to all interviews.
- Melius: *However, the issue is that NIOSH chooses the contractor to review NIOSH. If the RFP does not specify follow-up interviews, but that task is added later, would that require OMB approval?* Any task requiring an additional burden or time commitment from the public will require OMB approval.
- Ziemer: What constitutes an audit requires clarification; it is not a re-interview with different questions. It must be ensured that the ABRWH does not end up doing the work of the auditor or the agency itself. Mr. Griffon supported the generation of a transcript.
- Melius: The current QC plans, of having a supervisor listen in occasionally and informally, are not adequate. It is independent of the ABRWH's process, but that process still should be examined in more detail and improved. He was uncomfortable with substituting that for this Board's review. He asked the *Board to agree whether 1) the interview process should be reviewed by the ABRWH, and 2) how and when that should be done (e.g., transcript, with or without follow up interview; and after the record is developed or at the time of the initial interview?); and 3) how to implement that, while allowing NIOSH to proceed with the RFP.* For example, consideration is needed of whether the contractor has the necessary expertise to oversee the interview process.
- Dr. Andrade strongly suggested, if supervisors will be listening in randomly, that the supervisor and interviewer independently transcribe their summary of the interview (while redacting Privacy Act material). This should allow the OMB process to be completed quickly.
- Dr. Anderson thought that this would not require altering the Task Order. He suggested extending Task #1 with "or other evaluation mechanisms which would not increase the

time needed," or whatever the exclusionary phraseology would be. An independent auditor sitting in on the interview would not affect the claimant's time, nor would tape recording it. Those suggestions, or some other language (along with these meeting minutes), should indicate to the contractor the basis on which to estimate. He thought Item #1 to be overly restrictive and not even include auditing the independent record. If the only way to properly audit is a re-interview, that can be approached at another time.

- Dr. Ziemer expected that an independent listening-in by a Board member, separate from the audit and before the dose reconstruction itself is done, could focus on the process rather than the particular case, to identify shortcomings in the process.
- Melius: *Include a task for the contractor to develop a process, for submission to the Board, to evaluate the interview process.* Mr. Elliott responded that this is not the Task Order itself, but just a description for the bidders. The proposal would not have to bid on it, but would need to factor in the required expertise of technical personnel to respond to that. Once the Board has a technical consultation contractor in place, then the Task Orders will be developed and negotiated with the contractor.

  Resolution of the question. Dr. Ziemer suggested, to general agreement, deleting the last half of the sentence and inserting a period after "history of information" in Page5, 2.B1. This was to be done by Mr. Griffon after this document review.

Page 6, Section B; page 7, Section C: The numbers of cases projected were deleted. The estimated dose reconstruction reviews for individuals, but not site profiles, were inserted. Dr. Neton noted the need, for the procurement, to provide numbers for all years if numbers are provided for year one. Those could be reinserted before this meeting's end, as Mr. Griffon had already estimated them.

Mr. Elliott advised also **for Page 7, C-4, Task Orders, after sentence one, inserting the critical staff needs expected (e.g., for evaluation of survey instruments or for an expert on program evaluation), or "See attachment A, Personnel Requirements."**

Attachment A: Technical Evaluation Criteria

- Section A, Personnel, should be edited as just discussed.

Section E was modified in terms of the time allowable since DOE work was done, and key personnel are defined at the bottom of page 4.

Roessler: The work history (page 4, paragraph 2), "while performing with NIOSH, ORAU or "teaming partners" is too vague and should be more specific. Make this the "two primary teaming partners;" the procurement officer can name the corporations or insert the contract numbers. For example, ORAU has contracts for similar work not pertaining to this project at all.

- Mr. Griffon stated that the original intent was to be more restrictive about work with NIOSH or ORAU, as with DOE, to ensure the project's credibility to the public.
- Dr. DeHart objected that such excluded work could be one lecture delivered at ORAU four years earlier, or someone doing work with funding channeled through ORAU, but not actually done directly for or by them (e.g., training done oversees).

- It was agreed that the emphasis should be on disclosure. For example, insert "If work was done and those doing the work are included on staff, provide justification of why they are included."
- Mr. Elliott cautioned that this could exclude people who otherwise could develop a great proposal. Mr. Griffon thought that the justification should resolve that, but the minimum requirement could block out such people.
- Dr. DeHart asked if experts testifying for employees of AWEs would also be excluded, being concerned about excluding experts on only one side. His experience with compensation claims indicated that experts can disagree based on the same data, so excluding an entire viewpoint would skew objectivity. While the problem pertaining to individual claim cases had been resolved by the Board (experts just could not review any case in which they had testified), the problem facing class action suits still required resolution.

Review of Methods and Procedures

After a short lunch break, the discussion continued. Mr. Griffon noted that Task #1 in Attachment C had originally been to review methods and procedures, but this was rolled into the individual dose reconstruction review component. That was done because this review mostly pertained to the individual case audit process rather than that overall, particularly in the initial absence of real data/cases. It remains in the individual case approach. But he had reconsidered, since this also pertains to the path taken by NIOSH/ORAU. It would add value by independently reviewing the methods and procedures to establish an early baseline. The only intent is to establish a baseline and set an early understanding of how NIOSH/ORAU are approaching things. The EEOICPA statute itself also calls for review of the methods and a sampling of the cases, but this should be carefully bound to avoid great expense.

He suggested that this overall review be reinserted into Task #1, to enable a cost effective initial review. Aside from the individual case reviews, this could serve as the baseline of the NIOSH and contractor dose reconstruction process and allow resolution of any basic disagreements before many cases are adjudicated. It was currently a component of Item A, or it could be on page 4 under C-3. A handout distributed at this meeting proposed an 8-item methodology to review NIOSH and the contractor's methods/procedures (see Attachment #2 to this report).

Discussion with Mr. Griffon included:

- Andrade: The tasks as stated are quite general. The Board could appear to be second guessing what the experts themselves had developed, and the IREP and methods to address individual cases had been shown to be as claimant-friendly as possible. Finally, many if not most of the methods in the current processes had been presented to the ABRWH, many members of which also are experts, who agreed that these were the best methods for the analyses. This may go beyond the realm of auditing and approach second guessing. On the other hand, Mr. Griffon pointed out that reinserting it could also eliminate any second guessing since is done up front. He also clarified that this was not intended to second guess IREP or any other underlying level of the current approach.
- Ziemer: The procedures and questionnaires for the work history phone interviews have not yet been reviewed either. His sense was that the workgroup was not questioning the

approaches used, but whether those already described were being used. Mr. Griffon responded that the internal/external implementation guidelines address how, for example, a missed dose would be handled. This does not preclude individual case approaches that might have to differ, but would be only a generic review of the protocols (e.g., one question may be whether it is always sensible to assign an Minimum Detectable Activity (MDA) model).

Melius: Any review process involves some second guessing, but the Board should not revisit issues already addressed. This should be a carefully specified review of the application of the developed guidelines and procedures. Any identified vagueness or areas of potential uncertainty or disagreement could then be brought by the contractor back to the Board for resolution. This could be helpful to the overall review process, ensuring consistent application of these procedures, and would be more efficiently done up front.

Roessler: Clarity on the intent is necessary, to avoid interpretation by potential bidders that this could invite assessment of whether the proper ICRP guidelines are being used. But Mr. Griffon responded that, while the use of the proper ICRP model could be assessed, whether or not to use an ICRP model would not be. But these tasks also were deliberately broadly defined, as they only serve as place holders, since this work is not something that would be bid on in Attachments D and E. Nonetheless, it will need to be carefully bound in any actual Task Order.

DeHart: Agreed, the bidding contractor will have to understand the methodologies and procedures to bid. But should this be called an audit or report? Dr. Ziemer noted that a review for familiarity differs from an audit review.

Anderson: Add these issues to the first paragraph; especially the last part: "to achieve consistent application of the requirements of 42 CFR 82." Then, just drop the listed tasks.

Elliott: This was addressed in the early Board deliberations and in the workgroup, and the scope of work's items for the three reviews (basic, advanced, and blind reviews), call for address of any deficiencies. Additionally, a single review will not be sufficient. As the AWE technical guideline is developed, the review contractor will have to do several "snapshots in time" based on accumulated experience.

Dr. Neton agreed. The program is essentially keeping one step ahead of the dose reconstruction process; every possible scenario cannot be predicted. This is not a mature program that can be reviewed for a full fleshing-out of tables, etc. No contractor has ever done this kind of work, which is very different from regulatory-based or research dose reconstructions, although those can give the bidders some idea of the procedure. The first pass-through will look at a small set of the ultimate overall number of procedures, and the Board can pick the cases for review (low- versus high dose, etc.) and "road test" those.

Melius: *Take paragraph 1 and move it into the individual dose reconstructions, making it a second or third paragraph under the existing item A.* The Task Orders then could direct the contractor to avoid unnecessary or too-early reviews and time/target the reviews most appropriately.

Elliott: Change *"determine" to "evaluate;" and later in the sentence, insert "whether" before "there are sufficient procedures..."*

Andrade: *Or, insert a piece of last sentence into the provisions, addressing "whether the procedures in place are sufficient to achieve consistent application of the provisions of 42 CFR."* But this also is a secondary function, part of the audit. An audit is done by an

independent body to see how well the program is being done. The question is whether the Board will hire someone to do an audit (which he favored) or some other function. If an audit is done, he advised doing one comprehensive one, reviewing all the books rather than just one dose reconstruction or procurement. Audits are based on data arriving after the fact – e.g., reviewing two sets of transcripts of interviews in random fashion, choosing cases that are reflective of the number of cases coming from different sites. This is not to be confused with the QA function of the OCAS and ORAU supervisors. Finally, the OCAS dose reconstruction team leader is responsible for consistency of approach. That should be taken advantage of, ensuring that the Board is kept up to date. The focus should be on issues that need address, not those handled in other ways.
Anderson: This seems to be only spot where cross-program consistency is addressed, such that the procedures in place are documented and maintained in a continuing program that will inform the address and resolution of any future ambiguity found. Drs. Andrade and Neton agreed; these will be dynamic procedures that will develop over time. Being fundamental and consistent with the legislation, they will probably not change wildly, but some change is probable as specifics arise, not all of which can be documented.
Melius: If the contractor, in reviewing the procedures, raises an issue (e.g., the absence of a procedure to deal with a specific in a consistent manner) that has not risen in the first 2000 cases, that should be just a point to note, not a deficiency in the audit.
Munn: In the absence of precise language, Ms. Munn agreed with Dr. Andrade that overly prescriptive text should be avoided, which could establish criteria for a project that has never been done before. It would be hard to identify how many actions the auditor might be asked to undertake without defining what a full scale audit would involve.

Board Discussion/Working Session to Review All Documents

In a complete review of the documents, the Board commented on each section, as follows:

Request for Contract: No further changes were suggested to the document. The following Executive Session of the Board will insert the dollar amounts, and the Board member will be appointed to panel along with the OCAS project officer (Dr. Neton).

Attachment C: Statement of Work

C.1: Purpose of Contract : no changes

C.2: Background and Need: no changes

C.3: Contract Tasks
Component #1: Individual dose reconstructions

Section A: Dr. DeHart ***moved to insert after paragraph one, as a separate paragraph, text then read by Mr. Elliott: "The contractor shall review all relevant dose reconstruction methodologies and/or procedures employed by NIOSH and NIOSH contractors in conducting individual dose reconstructions in SEC petitions. The contractor shall***

evaluate whether the methodologies and procedures are consistent with the requirements under 42 CFR 82, and whether there are sufficient procedures to achieve consistent application of the requirements in 42 CFR 82."

The motion was seconded by Dr. Melius. There was no further discussion other than Mr. Griffon's remaining feeling that it may be confusing to place this under individual dose reconstruction review. He still preferred this as a separate task. *In a vote, **the motion was unanimously approved, including by Ms. Munn on the telephone link.***

Other considerations were:

- DeHart: *From where did the estimated case review numbers in C.3.A the current paragraph 2, now paragraph 3, come?* Griffon: These came from discussions with Dr. Neton and NIOSH staff, after which he adjusted the first year's expectations down considerably. Dr. Neton added that, if this process parallels the ORAU ramp-up, the realistic number of cases is expected to be less than the 8000 for year one.
- Dr. Andrade proposed again dropping the basic, advanced, and blind reviews, and instead having the contractor conduct a complete audit to determine the adequacy and correct use of the date and performance of the dose reconstruction. The points of the discussion included:
  - Anderson: A comprehensive audit might break the budget; doing a statistical sample could accomplish the intent.
  - Ziemer: The whole data base is available for audit and the ABRWH is the auditor, helped by a contractors to determine whether sampling 2% or 50% is an adequate sampling size. All the cases cannot be done.
  - Andrade: Agreed; base it on the number of claims from each site. But do a comprehensive study of each element of whatever cases are chosen.
  - Melius: After the first year, the Board can review whether the number audited is satisfactory. This would start the process, and later on it can be determined how the sampling will be done. This could be discussed during the selection process, but in the meantime, this the personnel that might be needed could be indicated.
  - Ziemer: Add: *These percentages are subject to change by the advisory Board based on its experience with the review process.*

Item C, 5d: Change the text to data *"are"* here and consistently throughout the document

Advanced Review.

- B.1: End the sentence after the work "information" and drop the comparison of NIOSH OCAS work history with the interview report. **No objections.** Griffon: Less specificity is acceptable here but he hoped, after this document was done, to discuss those specifics. He will edit attachments D&E to reflect this change.

Component #2, NIOSH OCAS site and worker profile reviews.

- Add an additional paragraph to cite the number of worker and site profile reviews (five and 5, respectively, in year one; 4 and 4 in years 2 and 3; and 3 and in year 5). This will total ~10% (32) of all covered facilities (~300). **No objections**
- Again, correct the grammar to "are ... data appropriate"

Component #3, Review of SEC Petitions (place marker, as no SEC rule is yet in place).

- Inserting the number of petition reviews per year of the contract was discussed, or text about the number "to be determined by the Board." However, this is not necessary in this document; and since the process/procedure remains unknown, it was agreed by **consensus to drop the numbers in the absence of the Rule.**

Component #4, Task Orders

- Insert ***"See Attachment A"*** after "the required work" in paragraph one.
- Item f: ***delete "of is projection".***

Component #5: Preparation of Reports: No changes

Dr. Melius **moved to approve Attachment C** and Mr. Espinosa seconded the motion. In a **vote, all Board members were in favor of the motion and none were opposed or abstained.**

Attachment D: **Example of Basic Individual Dose Reconstruction Review**
Mr. Griffon expressed concern that this attachment provides insufficient information for the bidders to respond. Dr. Neton clarified that what is being evaluated is their approach, more than the cost estimate (i.e., NIOSH assigned points to expertise of staff, approach, etc.). A bidders conference call could be held to address any such questions, and they also can state their assumptions (e.g., a 5-page versus a 100-page report). The most qualified bidders will understand the types of sites, and CDC's Procurement Office advises against including too much information in order to be able to assess what the bidder intuitively or by experience knows.

Dr. Anderson **moved to adopt Attachment D with no changes,** and Dr. DeHart seconded the motion, which **passed unanimously with no abstentions.**

Attachment E, Example of Advanced Individual Dose Reconstruction Review.
Dr. DeHart **moved to accept Attachment E** with the following edit: insert a period after 'information' in B.1 and dropping the rest of the sentence (as done for C3, Advanced Review). Dr. Andrade seconded the motion, which was **unanimously approved with no abstentions.**

Attachment A: **Technical Evaluation Criteria**

A. **Personnel** changes discussed were:

- Add an Item 7 after "6) evaluating contradictory records", to state: "7) program evaluation expertise related to health surveys" and then continue with "evidence of this..." **Agreed to by consensus.**

  Roessler: *Does text at the end of paragraph 2 on DOE Q clearance conflict with Section E's minimum of 2 years of non-DOE work by key personnel.* Mr. Gibson responded that this pertains to U.S. government clearance after a background check. Dr. Andrade noted that there are many different types of Q clearances: DOE and their contractors are cleared